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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,229	01/23/2002	Jose Remacle	VANM213.001CPI	6914

20995 7590 11/02/2006

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EXAMINER
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WOOLWINE, SAMUEL C

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/056,229	REMACLE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 13-18, 20, 21, 25-27, 30-33, 35, 38-40, 44-61, 81, 84-87 and 89-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1-8,11,13-18,20,21,25-27,30-33,35,38-40,44-61,81,84-87 and 89-94.

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment filed 7/31/2006 has been entered and considered.

Claims 1-8, 11, 13-18, 20-21, 25-27, 30-33, 35, 38-40, 44-61, 81, 84-87, and 89-94 are pending.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11, 13-18, 20-21, 25-27, 30-33, 35, 38-40, 44-61, 81, 84-87, and 89-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 9-10, 12-23, 38, 40, 42, 44-45 of copending Application No. 09/817014. Although the conflicting claims are not identical,

Art Unit: 1637

they are not patentably distinct from each other because the only differences in the limitations of the independent claims (claim 1 in both applications) are the following:

- claim 1 of the '014 application is directed to *an organism* whereas claim 1 of the instant application is directed to *a biological organism* (no difference in scope since all organisms, even viruses, can be considered "biological");

- claim 1 of the '014 application is directed to amplification *by PCR* whereas claim 1 of the instant application is directed generically to *amplifying* (PCR is a species of amplification which renders generic amplification obvious);

- claim 1 of the '014 application is directed to primer pairs *capable of amplifying at least two* [of four] *said homologous sequences* whereas claim 1 of the instant application is directed to primer pairs *capable of amplifying at least four* [of four] *said homologous sequences* ("at least two" encompasses "at least four");

- claim 1 of the '014 application is directed to a nucleotide spacer of *at least 40 bases* whereas claim 1 of the instant application is directed to a nucleotide spacer of *greater than 40 bases* ("at least 40" encompasses "greater than 40");

- claim 1 of the '014 application is directed to a capture sequence comprising a *nucleotide sequence of about 15 to about 40 bases* whereas claims 1 of the instant application is directed to a capture sequence comprising a *nucleotide sequence of about 5 to about 60 bases* (15 is "about" 5, and 40 is "about" 60).

- claim 1 of the instant application includes a *consensus capture nucleotide sequence* whereas claim 1 of the '014 application does not (it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant

Art Unit: 1637

application was made to include a consensus capture nucleotide sequence, since this would provide a confirmation of any positive result obtained with a specific capture sequence directed to a particular one of the at least four said homologous target sequences).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, as the claims of the '014 application have been allowed, and issue is pending, this rejection is maintained until such time as a terminal disclaimer is received by the Office.

Claims 1-8, 11, 13-18, 20-21, 25-27, 30-33, 35, 38-40, 44-61, 81, 84-87, and 89-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-10, 13, 16-17, 19-25 of copending Application No. 10/111748. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences in the limitations of the independent claims (claim 1 in both applications) is the added limitation in claim 1 of the '748 application that the homologous sequences to be amplified share more than 60% homology, specific primer sets for amplification are required, and no spacer is required to link the capture oligonucleotides to the solid support. Thus claim 1 of the '748 application represents a species of the more generic claim 1 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 11, 13-18, 20-21, 25-27, 30-33, 35, 38-40, 44-61, 81, 84-87, and 89-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/860388. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences in the limitations of the independent claims (claim 1 in both applications) is the added limitation in claim 1 of the '388 application that the homologous sequences to be amplified share more than 85% homology, and at least 2 sets of primer pairs are required to be used. Thus claim 1 of the '388 application represents a species of the more generic claim 1 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments, see page 11 of the response, filed 7/31/2006, with respect to the 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejection of claims 11, 36 and 81 have been fully considered and are persuasive. In particular, claim 36 has been cancelled, the amendment to claim 11 has clarified the previous ambiguity, and the explanation of antecedent basis for claim 81 is satisfactory. The rejection of claims 11, 36 and 81 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph has been withdrawn.

Applicant's arguments, see pages 11-13 of the response, filed 7/31/2006, with respect to the 35 U.S.C. 102 rejection of claims 1-8, 11-14, 18, 22, 23, 25-27, 29-34, 39-

Art Unit: 1637

40, 44-45, 55-57, 59-61, 81, 83 and 87 have been fully considered and are persuasive. The rejection of claims 1-8, 11-14, 18, 22, 23, 25-27, 29-34, 39-40, 44-45, 55-57, 59-61, 81, 83 and 87 under 35 U.S.C. 102 has been withdrawn in view of Applicant's amendment to claim 1 to recite "a spacer comprising a nucleotide sequence greater than 40 bases".

Applicant's arguments, see pages 13-15 of the response, filed 7/31/2006, with respect to the 35 U.S.C. 103 rejection of claims 15-17, 20, 21, 28, 35, 36, 38, 46, 48-54, 58, 84, 86, and 89-94 have been fully considered and are persuasive, in view of Applicant's declaration under 37 CFR 1.132 showing unexpected results. There is no teaching, suggestion or motivation in the prior art to use a spacer comprising *at least 40 bases*. The rejection of claims 15-17, 20, 21, 28, 35, 36, 38, 46, 48-54, 58, 84, 86, and 89-94 under 35 U.S.C. 103 has been withdrawn.

### ***Allowable Subject Matter***

All pending claims are allowable subject to the filing of a terminal disclaimer over application 09/817,014, the claims of which application have been allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

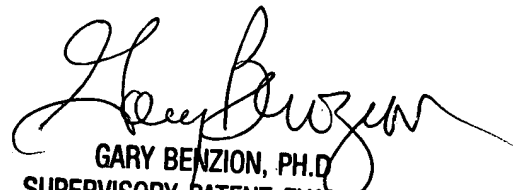
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SCW

  
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